THE UNITED STATES PATENT AND TRADEMARK OFFICE

BLACKSHEAR, William M., Jr.; FISCHER, Louise; and HAGEMEIER, Ralph

Serial No: **09/894,174** Group Art: 3626

Date Filed: June 27, 2001 Examiner: R. Rines

For: **MANAGEMENT METHOD OF PERSONS AT RISK OF COMPLICATIONS OF ARTERIAL OCCLUSIVE DISEASE**

Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION

William L. Blackshear, Jr., being duly sworn deposes and says that he is one of the inventors who, on June 27, 2001 filed the above identified application; that they completed their invention and disclosed the same to others in this country prior to September 1, 2000, as evidenced by the Letter Of Agreement between Tri-Med Management, Inc. and HealthHelp, Inc., dated July 8, 1999 (copy attached), more than one (1) year before the filing date of the application from which Crutchfield Patent No. 6,699,193 matured; that he does not know and does not believe that the invention had been in public use or on sale in this country, or patented or described in a printed publication in this or any foreign country for more than one year prior to their application, and they have never abandoned their invention.

Specifically, the invention referred to in the July 8, 1999 letter related to a classification and management system for patients with lower extremity arterial

occlusive disease. The system that comprises the following steps already developed at that time.

Specifically, the system comprises examining a patient at a healthcare facility with lower extremity arterial occlusion disease,

- collecting patient data including patient diagnoses, pertinent physical findings and noninvasive arterial pressure and blood flow data,
- recording the collected patient data,
- transmitting said collected patient data to an evaluating authority,
- comparing said collected patient data against a medically accepted set of disease specific criteria at the evaluating authority to provide an initial diagnosis and preliminary classification of those patients "potentially at risk" and those patients "not at risk" of developing complications of arterial occlusive disease,
- transmitting said preliminary classification to the healthcare facility,
- referring those patients classified as "potentially at risk" of arterial occlusive disease to an accredited laboratory for noninvasive vascular evaluation,
- evaluating those "potentially at risk" patients at the accredited laboratory against medically accepted criteria,
- recording the results of said noninvasive vascular evaluation at the accredited laboratory,
- transmitting said recorded results to the evaluating authority for final classification,
- classifying each patient at the evaluating authority against medically accepted criteria as "at risk" or "not at risk",
- transmitting said "at risk" or "not at risk" patient final classification to the healthcare facility,
- recording said "at risk" or "not at risk" patient final classification at the healthcare facility,
- referring patients having a final classification of "at risk" for critical ischemia with associated extremity lesions and patients with noninvasive evidence of severe ischemia to a vascular surgery facility for vascular surgical assessment to determine whether revascularization is necessary,
- assessing such "at risk" patients against medically accepted criteria as "clinical indication for operation" or "no indication for operation" at the vascular surgery facility,

- transmitting patient assessments assessed as "clinical indication for operation" or "no indication for operation" assessment to the evaluating authority,
- informing those patients assessed as "clinical indication for operation",
- electing either revascularization and periodic management system evaluation at the healthcare facility or routine wound care and periodic revaluation at the healthcare facility by patients assessed as "clinical indication for operation",
- monitoring patients assessed as "no indication for operation" by the healthcare facility with increased precautions to monitor for detection of any deterioration that would require reassessment,
- referring patients having ulcers, pain or gangrene at the time of "no indication for operation" assessment for reassessment,
- recording the reasons for not referring such patients as "clinical indication for operation",
- referring patients classified as "no indication for operation" that develop ulcers, pair and/or gangrene to the vascular surgery facility for reassessment,
- reassessing the referred patient at the vascular surgery facility against medically accepted criteria as "no indication for operation" or "clinical indication for operation",
- transmitting the reassessment of "no indication for operation" or "clinical indication for operation" to the evaluating authority for reevaluation as "no indication for operation" or "clinical indication for operation",
- transmitting the reevaluation to the healthcare faculty with the appropriate medical procedure and regimen,
- treating and monitoring patients classified as "not at risk", "at risk" and assessed as "no indication for operation" or "clinical indication for operation" at the healthcare facility,
- providing "not at risk" patients without limb ulcers routine care and precautions at the healthcare facility,
- providing "not at risk" patients with limb ulcers routine wound care at the healthcare facility,
- providing "not at risk" patients with limb ulcers periodic reevaluation by the evaluating authority,
- providing "at risk" patients assessed as "no indication for operation" or "operation not elected by patient", and "clinical indication for operation" patient undergoing revascularization at the vascular surgery facility with intensive wound care at the healthcare facility, and,
- providing periodic reevaluations of "at risk" patients assessed as "no indication for operation" or "operation not elected by patient" with increased precautions at the healthcare facility.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

William M. Blackshear, Jr.

LETTER OF AGREEMENT

After numerous conversations with Dr. Blackshear and Dr. Hagemeier there appears to be opportunities for HealthHelp, Inc., (HHI) and Tri-Med Management, Inc., (TMM) to work together. One area of interest for both parties is Beverly Nursing Homes, (BNH). In the event Beverly desires a comprehensive radiology vendor to service their residents in a fee for service or captivated arrangement, HHI would be interested in working with TMM to provide such services to BNH. Until we learn more about the potential client's desire to work with a radiology vendor the specifics of the partnership cannot be addressed. This letter serves as acknowledgment of the arrangement and involvement of HHI and TMM with regards to Beverly. It needs to be approved by TMM and will be an adjunct to their business not a competitor. TMM and their agents will not use any HHI proprietary information or products without written consent from HHI and will treat the information as confidential and will not try to compete with HHI or work with an HHI competitor with the same client. Likewise, HHI and their agents will not use any TMM propriety information or products without written consent from TMM and will treat the information as confidential and will not try to compete with TMM or work with a TMM competitor with the same client.

Both organizations require signing their Confidentiality and Technology Rights Agreement, which will be completed after review by their respective attorneys and before proceeding beyond the initial meeting with Beverly Nursing Homes.

By: William M. Blackshear

Dr. William M. Blackshear, Jr. M.D.

President

Tri-Med Management, Inc

Dated this 8th day of July, 1999

By: Charles Dudley Lee for RLS

Robin L. Smith, MD, MBA

Chief Medical Officer

HealthHelp, Inc.

Dated this 8 day of July, 1999